U.S.S.N. 08/924,994
FILED: SEPTEMBER 5, 1998
CLEAN VERSION OF CLAIMS AS AMENDED

Clean Version of Amended Claims
Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

sub E1

1. (Three times amended) A method for determining the level of an apolipoprotein in the serum of an individual based on levels of the apolipoprotein in the individual's saliva comprising

obtaining a saliva sample from an individual,

reacting the apolipoproteins in the saliva sample with antibodies immunoreactive with one or more of the apolipoproteins, wherein the antibodies are in a quantitative assay which measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith,

D1

determining the amount of apolipoproteins in the serum of the individual by comparing the immunoreactivity between the antibodies and apolipoproteins in the saliva sample by reference to standards of known amounts of apolipoproteins in saliva and serum.

D2

2. (Amended) The method of claim 1 wherein the apolipoprotein is selected from the group consisting of Apo A, Apo B, Apo C, and Apo E.

3. The method of claim 2 wherein the apolipoprotein is selected from the group consisting of Apo A1 and Apo B.

D3

4. (Amended) The method of claim 1 wherein the antibodies are labeled with a detectable label.

5. (amended) The method of claim 1 further comprising determining the level of apolipoprotein in the saliva sample within less than three hours following collection.

6. (twice Amended) The method of claim 1 further comprising preparing the saliva in the sample by removing mucopolysaccharides from the saliva prior to determining the level of apolipoprotein in the saliva sample.

7. (amended) The method of claim 1 further comprising collecting the saliva after stimulating its secretion from a subject.

8. The method of claim 1 further comprising determining the amount of albumin present in the saliva.

9. (twice Amended) The method of claim 8 further comprising correcting the determined amount of the apoplipoprotein for the presence of albumin in the saliva sample.

10. (twice amended) The method of claim 1 wherein the saliva sample is collected into a device which filters out mucopolysaccharides and which comprises the antibodies immunoreactive with one or more of the apolipoproteins in the saliva sample.

11. The method of claim 10 wherein the apolipoprotein is either Apo A1 or Apo B.

12. (amended) An assay device or kit for determining the amount of apolipoprotein in a saliva sample comprising

means for collection of saliva,

antibodies immunoreactive with one or more apolipoproteins, wherein the antibodies are in a quantitative assay which measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith, and

standards of known amounts of apolipoproteins in saliva and serum.

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13. (amended) The assay device or kit of claim 12 comprising filter means for removal of mucopolysaccharides from the saliva.

14. (amended) The assay device or kit of claim 12 wherein the antibodies are reactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, and Apo E.

15. The assay device or kit of claim 12 further comprising antibodies immunoreactive with albumin.

16. (twice Amended) The assay device or kit of claim 12 wherein the antibodies immunoreactive with apolipoprotein in the saliva sample are immobilized on a solid support.

17. The assay device or kit of claim 16 comprising reagents for detection of complexes between the apolipoprotein and the antibodies.

18. (Amended) The assay device or kit of claim 12 comprising a strip or dipstick.

19. (Amended) The assay device or kit of claim 15 comprising as separate reagents antibodies to the apolipoprotein and antibodies to albumin.

20. (Twice amended) A method for quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease from a saliva sample comprising

obtaining a saliva sample from an individual,

reacting the apolipoproteins in the saliva sample with antibodies immunoreactive with one or more of the apolipoproteins, wherein the antibodies are in a quantitative assay which

measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith,

determining the amount of apolipoproteins in the serum of the individual by comparing the immunoreactivity between the antibodies and apolipoproteins in the saliva sample by reference to standards of known amounts of apolipoproteins in saliva and serum from normal or at risk individuals.

21. (twice amended) The method of claim 1 further comprising,

correlating the levels of one or more lipoproteins selected from the group consisting of high density lipoprotein and low density lipoprotein, in the serum with the levels of apolipoprotein subtypes in the serum,

correlating the levels of the apolipoprotein subtypes in the serum based on the levels of apolipoprotein subtypes determined in the saliva sample, and

extrapolating the levels of the lipoprotein in the serum, based on the levels of the apolipoprotein subtypes determined in the saliva sample.

22. (amended) The method of claim 20 comprising reacting the apolipoprotein in the saliva sample with antibodies specifically immunoreactive with an apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, and Apo E, and

correlating the levels of at least one apolipoprotein in the saliva with the levels of apolipoprotein in serum samples of patients having lipid disorders or risk of cardiovascular disease.